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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,170	06/26/2003	Cathy Klech Gelotte	MCP 275 CON 2	8241

27777 7590 04/27/2005

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EXAMINER

JAGOE, DONNA A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/608,170	Applicant(s) GELOTTE ET AL.	
	Examiner Donna Jagoe	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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The amendment to the specification filed 28 January 2005 has been received and entered. Claims 18-42 are pending. The rejection of claim 28 made in the paper mailed 1 November 2004 under 35 U.S.C. §102(b) over Sunshine '465 ("Sunshine 1") is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant asserts that in making the rejection the examiner is required to point to the disclosure in the reference "by page and line", which the examiner has done. If there is any portion of the rejection that applicant does not understand, the applicant is encouraged to telephone the examiner. The phone number is provided below. Further, Applicant does not seem to be able to find where a suspension is found in the Sunshine reference cited. It appears in column 12, line 57 bridging to line 58. If applicant's objection is to the lack of the word "stable", it is unclear why any manufacturer would make an "unstable" suspension. By nature, all suspensions fall out and must be shaken before use, however this is not "unstable". It is merely a suspension by definition.

The rejection of claims 28-41 made in the paper mailed 1 November 2004 under 35 U.S.C. §103(a) over Sunshine '899 ("Sunshine 2") is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does

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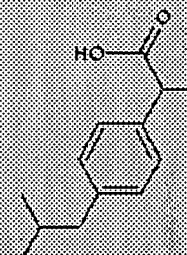
not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). It is well known that ibuprofen is insoluble in water and must be formulated into a suspension, as evidenced by the plethora of suspension formulations of ibuprofen in the marketplace.

The following prior art pertinent to applicant's disclosure is made of record and not relied upon.

IBUPROFEN

PRODUCT IDENTIFICATION

CAS NO.	15687-27-1
EINECS NO.	239-784-6
FORMULA	$(\text{CH}_3)_2\text{CHCH}_2\text{C}_6\text{H}_4\text{CH}(\text{CH}_3)\text{COOH}$
MOL WT.	206.29
H.S. CODE	2916.39
TOXICITY	ORL-RAT LD50:636 MG/KG



SYNONYMS 2-[4-isobutylphenyl]propionic Acid; Apsifen; Apsifen-F; Alpha-Methyl-4-(2-methylpropyl)benzeneacetic acid; Acide (Isobutyl-4 Phenyl)-2 Propionique (French); Ibuprocin; para-Isobutylhydratropic acid; (+/-)-2-(p-isobutyl phenyl)propionic acid; (+)-2-[4-isobutyl phenyl]propionic acid; 4-isobutyl- alpha-methylphenylacetic acid; Ibufen; Ibuprin; Alpha-methyl-4-(2-Methylpropyl)- Benzeneacetic Acid;

DERIVATION

CLASSIFICATION

PHYSICAL AND CHEMICAL PROPERTIES

PHYSICAL STATE	white crystalline powder
MELTING POINT	75 - 78
BOILING POINT	
SPECIFIC GRAVITY	

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SOLUBILITY IN WATER	Practically insoluble
pH	
VAPOR DENSITY	
AUTOIGNITION	
NFPA RATINGS	
REFRACTIVE INDEX	
FLASH POINT	
STABILITY	Stable under ordinary conditions

Further, regarding applicant's assertion that water is not contained in the composition, Sunshine et al. teach syrup formulations. The definition of a syrup, according to The American Heritage® Stedman's Medical Dictionary Copyright © 2002, 2001, 1995 by Houghton Mifflin Company is a concentrated solution of sugar in **water**, often used as a vehicle for medicine. Thus, even though water is not specifically recited, the presence of a syrup would include the presence of water.

The obviousness type double patenting rejection of claims 18-27 made in the paper mailed 1 November 2004 over claims 1-13 of U.S. 6,211,246 is maintained and hereby repeated for the reasons set forth in the previous office action. Since there are no other rejections are pending, these claims would be allowable with a timely filed terminal disclaimer.

The obviousness type double patenting rejection of claims 29-41 made in the paper mailed 1 November 2004 over claims 23-30 of U.S. 6,211,246 is maintained and hereby repeated for the reasons set forth in the previous office action.

The obviousness type double patenting rejection of claim 42 made in the paper mailed 1 November 2004 over claim 14 of U.S. 6,211,246 is maintained and hereby

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repeated for the reasons set forth in the previous office action. Since there are no other rejections are pending, this claim would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and with a timely filed terminal disclaimer.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

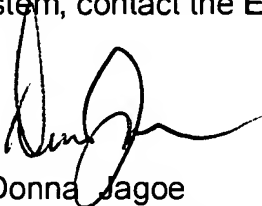
Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-0576. The examiner can normally be reached on Monday through Thursday from 9:00 A.M. - 3:00 P.M..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Donna Jagoe
Patent Examiner
Art Unit 1614

04/25/2005



CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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